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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/499,468	02/07/00	ALDERSON R	PF112U1

022195
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HM22/0530

EXAMINER	
SORBELLO,E	
ART UNIT	**PAPER NUMBER**
1633	11

DATE MAILED: 05/30/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/499,468	Applicant(s) ALDERSON ET AL.	
	Examiner Eleanor Sorbello	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 February 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, 15-17 drawn to a method of treating injury or degeneration of photoreceptors, by the administration of VEGF-2 classified in class 514, subclass 2.

II. Claims 12-14 and 18 drawn to a method for treating photoreceptor degeneration or injury by cell therapy or gene therapy, classified in class 514, subclass 44.

III. Claims 19-27, drawn to a composition comprising an antibody classified in class 424, subclass 130.1.

IV. Claims 28-33, drawn to a composition comprising an antibody and protein classified in class 424, subclass 130.1.

V. Claims 34-35, drawn to a composition comprising a specified first polypeptide linked to a specified second polypeptide, classified in class 424, subclass 130.1.

VI. Claim 36, 39 drawn to a method of proliferating cells in a patient by administering a composition comprising the antibody of claim 19, classified in class 435, subclass 7.1 *or* class 424, subclass 130.1.

VII. Claims 37, 40 drawn to a method of proliferating cells in a patient by administering a composition comprising an antibody and protein classified in class 435, subclass 7.1 *or* class 424, subclass 130.1 and 184.1 .

VIII. Claims 38, 41 drawn to a method of proliferating cells in a patient by administering a composition comprising a specified first polypeptide linked to a specified second polypeptide, classified in class 435, subclass 7.1 *or* class 424, subclass 130.1 and 184.1.

2. Inventions I, II, VI, VII and VIII are similar as they are drawn to methods of treating injury or degeneration of photoreceptors. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions I, II, VI, VII and VIII, use different modes of operation as they utilize distinct products.

3. Inventions III, IV and V are similar as they are drawn to distinct compositions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct effects and are not capable of being used together.

4. Inventions I, II, VI, VII and VIII are distinct from each other in that Invention I is drawn to a method of treating injury/degeneration which utilizes VEGF-2; whereas Invention II is drawn to a method of treating injury/degeneration which utilizes cell therapy or gene therapy; whereas Invention VI is drawn to a method of proliferating cells

in a patient utilizing an antibody; whereas Invention VII is drawn to a method of proliferating cells in a patient by utilizing an antibody and protein; whereas Invention VIII is drawn to a method of proliferating cells in a patient utilizing a specified first polypeptide linked to a specified second polypeptide. The inventions are distinct as each method requires a distinct product or has a distinct function.

5. Inventions III, IV and V are distinct from each other in that each is drawn to a distinct product or composition. Invention III is a composition comprising an antibody; whereas Invention IV is a composition comprising an antibody and protein; whereas Invention V is a composition comprising a specified first polypeptide linked to a specified second polypeptide. The inventions are directed to distinct compositions which are not capable of being used together, and have a distinct effects.

6. Inventions (III, IV, V) and (VI, VII, VIII) are related as product and process of use respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Invention III is a composition comprising an antibody and is related to Invention VI which is a method using the antibody of Invention III. However, Invention III (antibody) can be used in another materially different process, such as purifying of an antigen. Invention IV and VII are related as Invention IV is directed to a composition comprising an antibody and protein, whereas Invention VII is directed to a method of proliferating cells in a patient. However, Invention IV (antibody and protein) can be used in another

materially different process such as an *in vitro* assay. Invention V is a composition comprising a specified first polypeptide linked to a specified second polypeptide, whereas Invention VIII is directed to a method of proliferating cells in a patient by the administration of the aforementioned composition. However, Invention V (composition comprising a specified first polypeptide linked to a specified second polypeptide) can be used in another materially different process such as an *in vitro* assay. Therefore, for the reasons argued herein, Inventions III, IV, V, VI, VII and VIII are distinct.

7. Invention IV is distinct from Inventions I, II and III because Invention IV is drawn to a composition comprising an antibody; whereas Invention I is drawn to a method of treating injury/degeneration which utilizes VEGF-2; whereas Invention II is drawn to a method of treating injury/degeneration which utilizes cell therapy or gene therapy. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct effects and are not capable of being used together. Invention III is drawn to an antibody, whereas Inventions I and II are drawn to distinct methods using distinct products and have distinct effects.

8. Invention IV is distinct from Inventions I and II. Invention IV is drawn to a composition comprising an antibody and protein, whereas Invention I is drawn to a method of treating injury/degeneration which utilizes VEGF-2; whereas Invention II is drawn to a method of treating injury/degeneration which utilizes cell therapy or gene therapy. Inventions are unrelated if it can be shown that they are not disclosed as

capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct effects and are not capable of being used together. Invention IV is drawn to a product comprising an antibody and protein, whereas Inventions I and II are drawn to methods utilizing distinct products

9. Invention V is distinct from Inventions I and II. Invention V is drawn to a composition comprising a specified first polypeptide linked to a specified second polypeptide whereas Invention I is drawn to a method of treating injury/degeneration which utilizes VEGF-2; whereas Invention II is drawn to a method of treating injury/degeneration which utilizes cell therapy or gene therapy. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have distinct effects and are not capable of being used together. In the instant case Invention V is drawn to a composition which whereas Inventions I and II are drawn to methods that do not utilize the composition of Invention V.

10. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II, III, IV, V, VI, VII or VIII, restriction for examination purposes as indicated is proper.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. **NOTE:** **Group I**: contains claims directed to **patentably distinct species** for the "second agent". The "second agent" must be selected from the list, (see claim 16).

Group IV: contains claims directed to multiple **patentably distinct species** of the claimed invention. The claims encompass several antibodies and several proteins which must be selected from the list, (see claims 28-33).

Group V: contains claims directed to multiple **patentably distinct species** of the claimed invention. The claims encompass several first polypeptides. and several second polypeptides. Therefore both peptides must be selected from the list and be specified, (see claims 34-35).

Group VII: contains claims directed to multiple **patentably distinct species** of the claimed invention. The claims encompass several antibodies and several proteins. Therefore and antibody and protein must be selected from the list, (see claim 28).

Group VIII: contains claims directed to multiple **patentably distinct species** of the claimed invention. The claims encompass a first polypeptide fragment linked to a second polypeptide fragment which must be selected from a

list. The first and second polypeptide fragments must be specified and selected from the list, (see claim 34).

14. Applicant is requried under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

16. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

17. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Deborah Clark

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